

In the present Amendment, no substantive amendments were added to the claims. Claims 1 is amended to clarify typographical errors.

35 U.S.C. § 102 Rejections:

Claims 1-4, 6, 12, and 13 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,514,091 to Yoon (hereinafter "the Yoon patent"). The Applicant respectfully requests reconsideration of these rejections.

The present claimed invention discloses an intraluminal device for shaping a collapsed viscus. The device includes an elongated body member having at least three independent inflatable sections along the length of the body member, at least one tube positioned between adjacent inflatable sections, and a means for independently inflating each individual inflatable section to give shape to a collapsed viscus by acquiring its distended form when the inflated section is in the inflated condition. The inflatable sections are axially spaced along the body member and each inflatable section is axially fixed relative to the remainder of the axially spaced inflatable sections. Each inflatable section is designed to give shape to a collapsed viscus by acquiring its distended form when the inflated section is in the inflated condition. Each adjacent inflatable section extends around the entire circumference of the body. ^{38' in Applicant's invention} Each tube extends from a peripheral portion of the device between adjacent inflatable sections to a distal end of the body member wherein the tube is adapted to be selectively attached to a suction hose or a fluid supply source. This last feature is highlighted in the attached Fig. 2 of the present invention.

but the inflatable sections must have a means for inflating them

The Yoon patent is directed to a multifunctional instrument for performing various medical procedures at an internal operative site in the body. The instrument includes an elongated expandable member having a distal end for being introduced at the operative site through a relatively small size opening in the body, and a proximal end for being held externally off the body. The expandable member is movable between a non-expanded position wherein the expandable member has a first cross-sectional size to facilitate introduction at the operative site

through the opening and an expanded position. The expandable member has a second cross-sectional size larger than the first cross-sectional size. The device also includes a plurality of outer members for being disposed over a respective portion of the expandable member. The outer member constrains the respective portions against movement to the expanded position whereby the expandable member adjacent the portions form a plurality of protrudences when the expandable member is moved from the non-expanded position to the expanded position. The outer members are movable longitudinally along the expandable member to varied locations of the portions.

The Yoon patent does not teach or suggest tubes extending from a peripheral part of the device between adjacent inflatable sections that is attachable to a suction or a fluid supply source. This claimed feature is created for accessing luminal segments for supplying medication, removing body fluid, etc. The only embodiment in the Yoon patent having at least three independent inflatable sections along the length of the body member, as in the present claimed invention, is found in the attached Fig. 20 of the Yoon patent. This Figure illustrates the failure of the device in the Yoon patent of having suction/fluid supply tubes between adjacent sections.

Claims 2 and 3 of the present invention claim a body member that is a sleeve to be adapted to fit over an existing intraluminal tool, as well as individual fluid lines extending from each inflatable section to a distal end of the body member, as the means for independently inflating each section. The Fig. 20 embodiment of the Yoon patent does not teach the combination of the body member being a sleeve which is adapted to fit over an existing intraluminal tool with a body member having independent inflatable sections. Additionally, the Yoon patent, further does not teach individual tubes extending between inflatable sections.

With respect to claim 4 of the present invention, the Yoon patent does not suggest the plurality of suction/fluid supply tubes as claimed.

With respect to claims 12 and 13, Fig. 20 of the Yoon patent does not teach the shape of the inflatable sections in combination with the intraluminal device in claim 1.

Thus, claims 2-4, 6, 12 and 13 depend from and add further limitations to independent claim 1, and are deemed to be patentable for the reasons discussed hereinabove in connection with independent claim 1. Reconsideration of the rejection of claims 2-4, 6, 12 and 13 is respectfully requested.

35 U.S.C. § 103 Rejections:

Claims 5, 8, 9, and 11 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the Yoon patent in view of U.S. Patent No. 4,600,015 to Evans et al. (hereinafter "the Evans patent"). The Evans patent teaches a patient monitoring apparatus and method. The device can include positioning balloons 55 and 65 for positioning the device in the esophagus. Additionally, it includes provoking gastric balloons 52, 62, which are used to provoke contractions of the esophagus. Finally, sensing balloons 51 or 61 can be provided to provide patient monitoring. Additionally, the Evans patent discloses a possible use of fibre optic channels in the probes to enable assessment of the oxygenation of the mucosa of the patient to measure the general level of oxygenation of the patient.

The Applicant respectfully disagrees with the Examiner that it would have been obvious to one of ordinary skill in the art at the time of the invention to provide optical fibre materials, as taught by the Evans patent, in the Yoon patent device to access oxygenation of the mucosa of a patient. Claim 5 is dependent on claim 4 and independent claim 1 of the present invention. The Evans patent does not teach or suggest at least one optical scope position between adjacent inflatable sections and extending to a distal end of a body member with the intraluminal device in claim 1, including at least four adjacent inflatable sections where at least one tube is adapted to be selectively attached to a suction hose or a fluid supply source. The Evans patent rather discloses a patient monitoring apparatus, which may include fibre optic channels to measure the level of oxygenation of the patient. The Evans patent does not teach the use of optical fibres positioned between adjacent balloon sections nor does it utilize the optical fibres to provide a comprehensive view of the procedure to the surgeon. Furthermore, the Evans patent

does not disclose an intraluminal device for shaping a collapsed viscus having independent inflatable sections along the length of a body member where the independent inflatable sections are axially spaced along the body member and are individually inflatable sections. Additionally, the prior art does not teach or suggest a control panel as in claim 9 of the present invention. The claimed invention has a control panel wherein each fluid line, tube and optical scope is attached to the control panel. Thus, the Evans patent does not cure the deficiencies of the Yoon patent, as discussed hereinabove, and further does not teach or suggest the combination of the corresponding dependent claims with independent claim 1. Reconsideration of the rejections to claims 5, 8, 9, and 11 is respectfully requested.

Even if the cited combination fairly taught the Applicant's claimed invention, the rejection is improper because there is no basis for combining the patents.

It is a basic principle of the United States Patent Laws that it is improper to arbitrarily pick and choose prior art patents and combine selected portions of the selected patents on the basis of the Applicant's disclosure to create a hypothetical or fictional combination which allegedly renders a claim obvious, unless there is some direction in the selected prior art patents to combine the selected teachings in a manner to negate the patentability of the claimed subject matter. This principle was enunciated forty years ago by the Court of Customs and Patent Appeals in In re Rothermel and Waddell. 125 USPQ 328 (C.C.P.A. 1960) where the Court stated (p. 331):

The examiner and the board in rejecting the appealed claims did so by what appears to us to be a piecemeal reconstruction of the prior art patents in the light of appellants' disclosure. Thus one element of the claims, the inner reinforcing member, is found in Roberts to be 'covered' by the outer sheath because it is embedded therein. As to the deep corrugations of Roberts, we are told by the examiner and the board that they could be made less deep if one desired to provide a smooth surface on the interior of the hose. This assertion is made despite the teachings of Martin that the flexibility of the conduit will increase as the depth of the corrugations is increased.

It is easy now to attribute to this prior art the knowledge which was first made available by appellants and then to assume that it would have been obvious to one having the ordinary skill of the art to make these suggested reconstructions. While such a reconstruction of the art may be an alluring way to rationalize a rejection of claims, it is not the type of rejection which the statute authorizes. 35 U.S.C. 103 is very specific in requiring that a rejection on the grounds the invention 'would have been obvious' must be based on a comparison between the prior art and the subject matter as a whole at the time the invention was made. [Emphasis added.]

The Court of Appeals for the Federal Circuit affirmed a finding of claim validity by the District Court for the Northern District of Indiana in *Grain Processing v. American Maize*, 5 USPQ2d 1788 (Fed. Cir. 1988) stating (p. 1793):

Maize's effort to establish obviousness by showing that Each element of the patented products may be found somewhere In the prior art is also unavailing. In determining obviousness, 'the Inquiry is not whether each element existed in the prior art, but Whether the prior art made obvious the invention as a whole for Which patentability is claimed.' *Hartness Int'l, Inc. v. Simplimatic Eng'g Co.*, 819 F.2d 1100, 1108, 2 USPQ2d 1826, 1832 (Fed. Cir. 1987). Here, the cited references would not have been sufficient, either along or in Combination, to suggest the invention to one of ordinary skill in the art.

The same result was reached in *Smithkline Diagnostics Inc. v. Helena Laboratories Corp.*, 8 USPQ2d 1468 (Fed. Cir. 1988), wherein the Court states (p. 1475):

...Merely pointing to a negative monitor in the prior art, which constitutes Helena's main argument to establish obviousness, is unpersuasive. Helene cannot pick and choose among the individual elements of assorted Prior art references to recreate the claimed invention. *See, e.g., Azko N.V. v. United States Int'l Trade Comm'n*, 808 F.2d 1471, 1481, 1 USPQ2d 1241, 1246 (Fed. Cir. 1986), *cert. Denied*, 107 S.Ct. 2490 (1987). Helena has the burden to show some teaching or suggestion in the references to support their use in the particular claimed combination. *Uniroyal Inc.*, 837 F.2d at 1051, 5 USPQ2d at 1438-39. A holding that combination claims are invalid based merely upon finding similar elements in separate prior art patents would be 'contrary to statute and would defeat the congressional purpose in enacting Title 35.' *Panduit Corp.*, 810 F.2d at 1577, 1 USPQ2d at 1605.

The Court of Appeals for the Federal Circuit reaffirmed the proposition that combining prior art references requires a teaching or a suggestion in the references in *In re Gorman*, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991); *In re Vaeck*, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991) *Symbol Technologies Inc. v. Opticon Inc.*, 19 USPQ2d 1241, 1246, (Fed. Cir. 1991);

In Continental Can Co. USA Inc. v. Monsanto Co., 20 USPQ2d 1746 (Fed. Cir. 1991); In re Jones, 21 USPQ2d 1941 (Fed. Cir. 1992); Texas Instruments Inc. v. International Trade Commission, 26 USPQ2d 1018 (Fed. Cir. 1993); Heidelberger Druckmaschinen v. Hantscho Commercial Products, 30 USPQ2d 1377, (Fed. Cir. 1994).

The law has been clearly and consistently stated by the courts over the last 40 years. *There must be a teaching or a suggestion to support a combination of the teachings from a number of prior art references in order to reject claimed subject matter in an application as being obvious to one of ordinary skill in the art at the time an invention was made.*

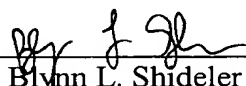
The applied combination created by the Examiner to reject claims 5, 8, 9, and 11 of the instant application is improper since there is absolutely no basis for the combination other than the hindsight provided by the Applicant's disclosure which may not be used as a blueprint or a template for selecting elements from different prior art references to create a hypothetical combination for the purpose of rejecting claims. Reconsideration of the rejections of claims 5, 8, 9, and 11 is respectfully requested.

CONCLUSION

For all of the foregoing reasons, the Applicant believes that claims 1-6, 8, 9, and 11-13 remain in this application, and are in condition for allowance. Reconsideration of the Examiner's rejection and allowance of claims 1-6, 8, 9, and 11-13 are respectfully requested.

Respectfully submitted,

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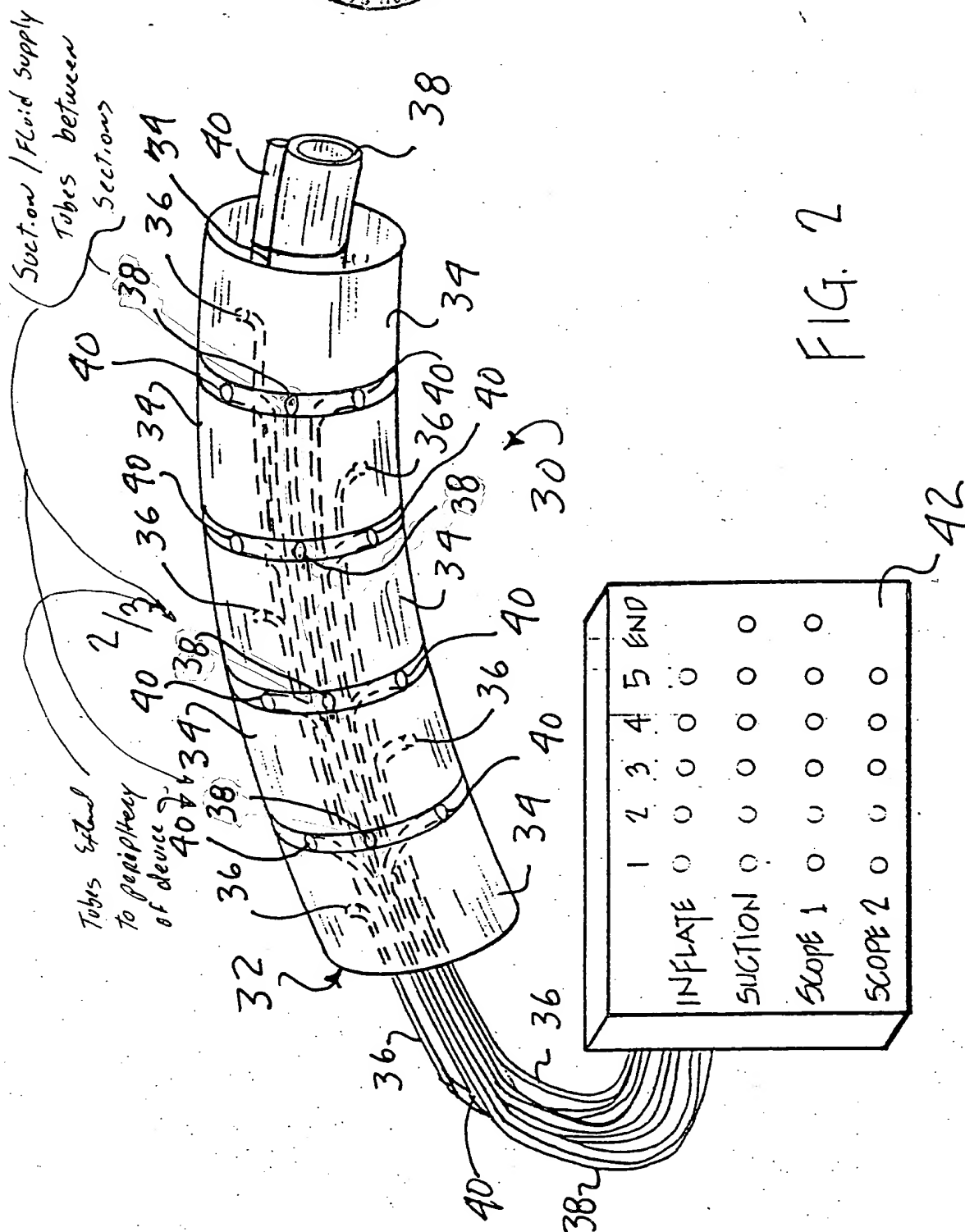
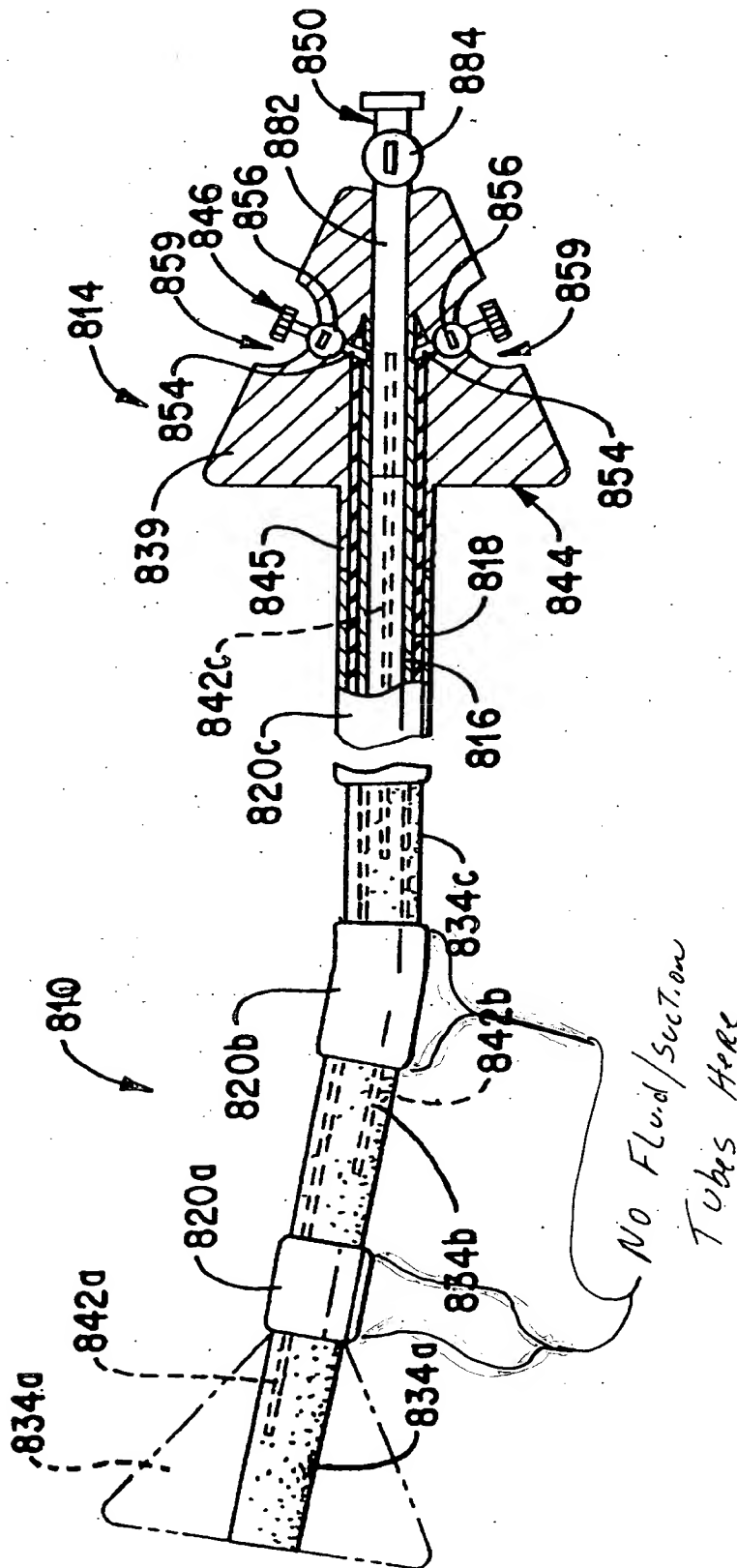


FIG. 2





PATENT APPLICATION
SERIAL NO.: 09/817,956
ATTORNEY DOCKET NO.: 2931-010557

The marked-up version of amended claim 1 is as follows:

1. (Twice Amended) An intraluminal device for shaping a collapsed viscus, the device comprising:

an elongated body member, the elongated body member having at least three independent inflatable sections along the length of the body member, wherein the independent inflatable sections are axially spaced along the body member and each inflatable section is axially fixed relative to the remainder of the axially spaced inflatable sections, and wherein each inflatable section is designed to give shape to a collapsed viscus by acquiring its distended form when the inflated section is in the inflated condition;

at least one tube positioned between adjacent inflatable sections, wherein each adjacent inflatable section extends around the entire circumference of the body, and wherein the tube extends from a peripheral portion of the device between adjacent inflatable sections to a distal end of the body member, wherein the tube is adapted to be selectively attached to a [section] suction source or a fluid supply source; and

a means for independently inflating each individual inflatable section to give shape to a collapsed viscus by acquiring its distended form when the inflated section is in the inflated condition.